REMARKS

Claim 18 has been amended. Thus, Claims 1-20 remain pending. No new matter has been added. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

The Examiner has objected to the drawings as failing to show the features of the present invention described in claims 10 and 11. Although, the Examiner cites claims 9 and 10, the language quoted in the Office Action is found in claims 10 and 11, which will be addressed. Claim 10, which depends from claim 9, states that "the desired ratio is one to one." Claim 9 states that "the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of flow at the first end to fluid flow at the second end." Reading claims 9 and 10, in view of the specification and Figure 1, one of skill in the art would understand that fluid entering the sheath via the hydration opening according to this specific embodiment will flow equally toward the first and second ends thereof. Thus, the ratio of flow at the first and second ends would be 1:1. It is respectfully submitted that those skilled in the art would understand that the opening according to this embodiment may be positioned and arranged in any manner which will achieve this result and no specific arrangement need be shown.

Claim 11 states that "the hydration opening is substantially equidistant from the first and second ends." In view of the specification and Figure 1, one of skill in the art would understand that upon unraveling the sheath, a distance from the first end of the sheath to the hydration opening would equal another distance from the second end of the sheath to the hydration opening. This may be understood by viewing the sheath as a hoop, as shown in Figure 1. Furthermore, it is respectfully submitted that, as patent drawings are not to scale, such a relationship in lengths is properly expressed in the specification and could not be inferred from any drawing features.

Therefore, it is respectfully submitted that the drawings show every feature of the

present invention specified in the claims, and, thus, the objections to the drawings should be withdrawn.

Claims 18 and 14 stand rejected under 35 U.S.C. § 112. In view of the amendment made to claim 18, it is respectfully requested that the rejection of this claim under § 112 be withdrawn. Claim 14, which depends from claim 13 which depends from claim 12, states that "the desired ratio is one to one." Claims 12 states that "the hydration opening is oriented to direct an amount of flow toward the first end which is different than the amount of flow directed toward the second end." It is respectfully submitted that, although a hydration opening may direct a different amount of flow to the first and second ends due to its orientation, a resulting ratio of the overall flows at the ends may be 1:1 (e.g., if the opening is not equidistant from the ends). Therefore, it is respectfully submitted that claim 12 fully complies with § 112 and it is requested that the rejection of this claim under § 112 be withdrawn.

Claims 1-9, 12, 13 and 15-17 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,569,106 to Ullman.

Claim 1 recites a protective package for an elongated medical device comprising "a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein *a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of elongated medical device*" and "a hydration opening disposed between the first and second ends of the sheath."

In contrast, Ullman describes a medical guide wire containment device consisting of a housing 11 having three individual isolation chambers 13-15 therein. Each chamber includes a funnel 18 extending externally therefrom for receiving a distal end of a guide wire 16. After being inserted into the funnel 18, the distal end follows a fixed spiraling guide 27 to ensure that the guide wire 16 spirals without entanglement. *Ullman*, col. 5, lines 13-17.

Applicants respectfully submit that neither the isolation chamber 13 nor the fixed spiraling guide 27 of Ullman is a protective sheath "wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device," as recited in claim 1. The isolation chamber 13 is simply an empty reservoir for receiving a portion of the length of the guide wire 16. The insertion of the guide wire 16 into the chamber 13 continues until a proximal tip 16a remains extending externally from the chamber 13. That is, the guide wire 16 is never fully encased in the chamber 13. In fact, Ullman states that "the wire is pushed all the way in [the chamber] until a small amount, such as about 1-2 cm, remains external to the membrane." *Ullman,* col. 2, lines 60-62. Thus, the tip 16a is never received by the chamber 13. Therefore, it is respectfully submitted that Ullman neither discloses nor suggests a protective sheath "wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device," as recited in claim 1.

It is respectfully submitted that, because claims 2-9, 12 and 13 depend from, and, therefore include all of the limitations of claim 1, these claims are also allowable.

Claim 15 recites a catheter kit comprising "a catheter having a shaped distal tip" and "a tubular enclosure having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter" in conjunction with "a first end of the tubular enclosure being adapted to receive the shaped distal tip" and "a second end of the tubular enclosure being adapted to received a proximal end of the catheter" and "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends."

Initially, it should be noted that Ullman does not disclose or suggest "a first end of the tubular enclosure being adapted to receive the shaped distal tip" and "a second end of the

tubular enclosure being adapted to received a proximal end of the catheter." As noted above, the tip 16a of the guide wire 16 remains external to the chamber 13, and, as such, is never received therein. Further, Ullman does not disclose or suggest a "hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends." A filling port 30 is used to fill or prime an inside the chamber 13 from a bottom to a top thereof. That is, Ullman does not teach that a saline solution inserted into the chamber 13 via the filling port 30 is directed in to the two ends (i.e., relies on gravity to fill the chamber 13 in one direction).

Therefore, Applicants respectfully submit that claim 15 is allowable. Because claims 16 and 17 depend from, and, therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Claims 1-7 and 9-14 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,588,588 to Samuels.

Applicants respectfully submit that Samuels neither discloses or suggests "a hydration opening disposed between the first and second ends of the sheath." Samuels describes a hoop packaging tube 40 consisting of a leading opening 44 and a trailing opening 48. An adapter 10 connecting the openings 44 and 48 includes a funnel 24 for receiving one or more guidewires 60. A guidewire 60 is inserted into the tube 40 via the adapter 10, winding wind around the tube 40 until the guidewire 60 has been fully inserted therein. At no point does Samuels teach or suggest that the adapter 10 is suitable for receiving fluid or that fluid inserted thereinto would hydrate the tube 40. In fact, Samuels states that "[a]fter the guidewire is reinserted into the packaging tube, the adapter 10 may be removed...and the bridge connector may be reinserted to close the loop of the packaging tube." *Samuels*, col. 3, lines 40-44. Thus, it is respectfully submitted that Samuels neither discloses nor suggests "a hydration opening disposed between the first and second ends of the sheath," as recited in claim 1.

Therefore, because claims 2-7 and 9-14 depend from, and, therefore include all of

the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claims 8 and 15-20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Samuels in view of Ullman. The Examiner states that Samuels discloses the invention substantially as claimed but does not disclose use with a catheter.

It is respectfully submitted that Ullman does not cure the above-described deficiencies of Samuels. Thus, because claim 8 depends from, and, therefore includes all of the limitations of claim 1, it is respectfully submitted that this claim is also allowable. With regard to claim 15, neither Samuels nor Ullman discloses "the hydration opening being positioned so that a desire proportion of flow thereinto is directed toward the first and second ends." Specifically, Samuels does not disclose or suggest that the adapter 10 or the tube 40 are suitable for hydration. As noted above, Ullman does not teach that saline solution inserted into the chamber 13 via the filling port 30 is directed in any manner toward the two ends of the chamber 13. Thus, it is respectfully submitted that neither Samuels nor Ullman, either alone or in combination, discloses or suggests, "the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends," as recited in claim 15. Because claims 16-20 depend from, and, therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Claims 1, 3, 6-9, 12, 13, 15, 16 and 19 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,861,395 to Taniguchi.

In contrast to the present invention, Taniguchi describes a catheter assembly 10 consisting of a body 12 and a protective bag 70 extending distally therefrom. As noted by the Examiner, Figure 3 of Taniguchi shows a connection between the body 12 and a proximal end of the protective bag 70. A distal end of the protective bag 70 is freely movable and does not attach to the body 12 in any manner. Thus, it is respectfully submitted that Taniguchi neither discloses nor suggests "a hydration opening disposed between the first and second ends of the sheath," as

recited in claim 1, or "a hydration opening extending into an interior of the tubular enclosure between the first and second ends thereof," as recited in claim 15. Because claims 3, 6-9, 12 and 13 depend from, and therefore include all of the limitations of claim 1, and, because claims 16 and 19 depend from, and, therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Claim 4 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Taniguchi in view of U.S. Patent No. 4,805,611 to Hodgkins. The Examiner states that Taniguchi discloses the invention substantially as claimed but fails to teach a luer or adapter capable of receiving a syringe. Applicants respectfully submit that Hodgkins does not cure the above-described deficiencies of Taniguchi. Thus, because claim 4 depends from, and, therefore includes all of the limitations of claim 1, it is respectfully submitted that this claims is also allowable.

Claims 1, 4, 7 and 9-11 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,597,264 to Laak.

Laak describes a leaching field consisting of a manifold for receiving effluent from a septic tank and directing the effluent through parallel outlets in the manifold. At no point does Laak disclose or suggest that the manifold includes "a protective sheath including a lumen sized to receive a body of *the elongated medical device*," as recited in claim 1. In fact, the manifold receives a continuous flow of effluent therethrough from a septic tank. As such, Laak never suggests that an elongated medical device is received in the manifold and subjected to contact with the flow of effluent. Further, one skilled in the art would not use Laak for such a purpose in view of the goals of sterility and prevention of infection/contamination, which are common in the medical field.

Therefore, Applicants respectfully submit that Laak neither discloses nor suggests "a protective sheath including a lumen sized to receive a body of *the elongated medical device*," as recited in claim 1. Because claims 4, 7 and 9-11 depend from, and, therefore include all of the

limitations of claim 1, it is respectfully submitted that these claims are also allowable.

CONCLUSION

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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